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Lead Counsel for Lead Plaintiff

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X

In re Shattuck Labs, Inc. Securities Litigation,

Master File No. 1:22-cv-00560-CBA-RML

CLASS ACTION

X

This Document Relates To:

ALL ACTIONS

CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

TABLE OF CONTENTS

Lead Plaintiff Scott Harrison and named plaintiff Andrea Viti ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Defendants (defined below), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters.

I. INTRODUCTION

1. This is a class action brought on behalf of:

   a. All persons who purchased Shattuck Labs, Inc. common stock pursuant or traceable to Shattuck's Initial Public Offering Registration Statement (defined below) in connection with Shattuck's October 13, 2020, Initial Public Offering before November 9, 2021, raising claims under Sections 11 and 15 of the Securities Act of 1933 ("Securities Act") against all Defendants; and

   b. All persons who purchased Shattuck common shares from February 17, 2021, through November 8, 2021, both dates inclusive, and who held such shares past November 8, 2021, raising claims under Sections 10(b) and 20(a) of the Exchange Act of 1934 ("Exchange Act", "Exchange Act Class Period") bringing claims against Defendants Shattuck, Taylor Schreiber, Josiah Hornblower, and Andrew Neill;

   c. The "Class" consists of all persons having claims under ¶1.a. and/or ¶1.b. hereof ("Class Members").

2. Shattuck develops immuno-oncology treatments. Its first treatment to enter clinical trials was SL-279252 (referred to herein as PD/OX, for reasons explained below). Shattuck was developing PD/OX with Takeda Pharmaceuticals, Inc., a pharmaceutical giant, through an agreement that had provided Shattuck with $75 million and access to Takeda's credibility and

know-how. Because the trial was open label, meaning that all patients received PD/OX, Defendants were kept abreast of the results. By the time of the IPO, 29 of 30 patients in the trial had been treated and nearly all had completed their treatment. Defendants had their results—and they were dismal. Only ***one*** patient had met Shattuck's pre-specified efficacy endpoint. Patients who received subtherapeutic doses actually did better than patients who received potentially therapeutic doses. The Phase I clinical trial showed PD/OX was not effective. Defendants violated Section 11 of the Securities Act because they were required to disclose as much in the Registration Statement, but did not.

3. Shattuck develops immuno-oncology treatments (i.e., treatments that aim to fight cancer by boosting the immune system's response). Shattuck's treatments are based on fusion proteins. These fusion proteins conjoin two molecules. One belongs to a group of molecules that blockade proteins that suppress immune response (i.e., they boost immune response by turning off the immune system's off switch). The other belongs to a group of molecules that activate immune response (i.e., they boost immune system response by turning on the on switch). Shattuck hypothesized that by using a single protein that turns on the on switch and turns off the off switch, its fusion proteins would stimulate a response more effective than proteins that only targeted an on switch or an off switch, even if two single-target proteins were taken in combination.

4. Shattuck develops these proteins using its proprietary platform, Agonist Redirected Checkpoint, or ARC. The platform allows Shattuck to develop numerous fusion proteins to target different forms of cancer.

5. Each fusion protein is a separate product requiring clinical trials and FDA approval.

6. Shattuck was founded in 2016. An August 2017 partnership with pharmaceutical giant Takeda Pharmaceutical Co. ("Takeda Agreement") jumpstarted its growth. It held its IPO on October 13, 2020, receiving gross proceeds of $232.3 million.

7. In the Takeda Agreement, Shattuck and Takeda had agreed to jointly develop PD/OX (and another molecule) through Phase I clinical trials. The Takeda Agreement assigned to Shattuck the legwork while providing that Takeda would reimburse most of the costs. In exchange, Takeda was granted an option to license either of the two fusion proteins after Phase I trials.

8. The first Shattuck product to reach clinical trials was a Takeda Agreement protein that inhibited PD-1 (an off switch) and activated OX40 (an on switch), SL-279252 ("PD/OX").

9. Ordinarily, clinical trials are double-blinded. None of the patients, the investigators who administer the drug, nor the sponsor, know whether any given patient is receiving the treatment or a placebo. The PD/OX clinical trial ("Clinical Trial") was open label. There was no placebo control group; every patient received PD/OX.

10. Phase I clinical trials take on a critical role in cancer treatments. Almost half of cancer treatments are submitted for approval after only two phases of clinical trials, rather than the more typical three or more. That means sponsors must use Phase I clinical trials to select the dose and dose schedule for the pivotal clinical trial. Thus, Phase I clinical trials must at least demonstrate some efficacy and identify the dose at which the product is effective.

11. The Clinical Trial was a dose escalation study with ten dose levels. Each dose was assigned a predetermined number of patients (though the numbers were not identical). Shattuck would start by treating the patients it recruited with the lowest dose. Once Shattuck filled out the lowest dose cohort, it would assign patients to the next lowest dose. Shattuck would continue filling out doses until it completed highest dose cohort.

12. To establish that PD/OX was safe, the FDA required Shattuck to first treat patients with subtherapeutic micro-doses that were far too low to have a clinical impact. This group of 10 patients thus served as a makeshift control group, though unlike placebos, the patients knew that they were getting PD/OX and at what dose.

13. The potentially therapeutic doses were 0.3mg/kg, 1.0mg/kg, 3.0mg/kg, and 6.0mg/kg. The subtherapeutic doses ranged from 0.1mg/kg to as little as 0.0001mg/kg.

14. Shattuck was promptly informed of any developments. Shattuck adapted its practices from its partner Takeda. According to a Takeda insider on the PD/OX team, in open-label trials, Takeda is informed of a patient's withdrawal (including because of death) within at most a day, and of patient results within a similar timeline.

15. The Clinical Trial began enrolling in May 2019. According to the Takeda insider, almost all of the dose escalation patients had begun treatment by April 2020. By September 9, 2020, or 29 days before the IPO Registration Statement was declared effective, 29 of 30 patients had received treatment. By the time of the IPO, nearly all the outcomes from the Clinical Trial were in—and they were bad.

16. Shattuck had pre-selected two metrics to evaluate efficacy: clinically meaningful reductions in tumor size and stable disease (as defined in the field of oncology) for at least 12 weeks.

17. Only one patient achieved clinically meaningful reduction in the size of his or her tumor for any length of time. That patient received 1.0mg/kg, almost the smallest potentially therapeutic dose.

18. Nor did PD/OX stabilize patients' cancers. 30% of patients who received subtherapeutic doses, but only 16% of patients who received therapeutic doses, achieved stable disease.

19. The Clinical Trial not only called into question PD/OX's viability, it also imperiled the Takeda Agreement. The Takeda Agreement had accounted for substantially all of Shattuck's pre-IPO revenues. Indeed, at $75.7 million, revenues from the Takeda Agreement had accounted for one third of all Shattuck's pre-IPO financing. Takeda was also providing Shattuck with invaluable credibility and know-how. Without Takeda, Shattuck's future was uncertain.

20. Congress has imposed high disclosure standards on companies that sell their stock to the public. That the Clinical Trial indicated that PD/OX was ineffective falls well within those disclosure obligations. Defendants breached their duties by failing to disclose the Clinical Trial's poor results when they raised $232.3 million from investors who had a legal right to be informed.

II. JURISDICTION AND VENUE

21. The claims alleged herein arise under and pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act (15 U.S.C. §§77k, 771(a)(2) and 77o) and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §22 of the Securities Act and 28 U.S.C. §1331 and §27 of the Exchange Act.

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and §22(a) of the Securities Act (15 U.S.C. §77v(a)) as a significant portion of the Defendants' actions and the subsequent damages took place within this District and §27 of the Exchange Act (15 U.S.C. §78aa)

and 28 U.S.C. §1391(b) as the alleged misstatements entered and subsequent damages took place within this District.

24. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of a national securities exchange. Defendants disseminated the statements alleged to be false and misleading herein into this District, and Defendants solicited purchasers of Shattuck securities in this District.

III. PARTIES AND WITNESSES

25. Plaintiffs, as set forth in their PSLRA certifications which were previously filed and are incorporated by reference herein, purchased the Company's securities at artificially inflated prices pursuant or traceable to the Registration Statement before November 9 and were damaged thereby.

26. Defendant Shattuck is a clinical-stage biotechnology company. It develops fusion proteins using its proprietary Agonist Redirected Checkpoint (or ARC) platform, which was developed by scientists at the University of Miami. Shattuck's most advanced product is PD/OX, which it is developing in collaboration with Takeda. Since its October 13, 2020, IPO, Shattuck common stock has traded on the NASDAQ under the ticker symbol "STTK."

27. Defendant Taylor Schreiber co-founded Shattuck and has been a director since its founding. He has served as its CEO since January 2020.

28. Defendant Andrew Neill was at the time of the IPO Shattuck's Vice-President of Finance and Corporate Strategy. Since March 2021, he has served as the Company's CFO.

29. Defendant Josiah Hornblower co-founded Shattuck and served as its CEO until January 2020, when he left his post to become its Executive Chairman and one of its directors. His tenure at Shattuck, including his position as a director, ended in October 2021.

30. Defendant Helen M. Boudreau was a Director of the Company at the time of the IPO.

31. Defendant Neil Gibson was a Director of the Company at the time of the IPO.

32. Defendant George Golumbeski was a Director of the Company at the time of the IPO.

33. Defendant Michael Lee was a Director of the Company at the time of the IPO.

34. Defendant Tyler Brous was a Director of the Company at the time of the IPO.

35. Schreiber, Neill, Hornblower, Boudreau, Gibson, Golumbeski, Lee, and Brous are the "Individual Defendants."

36. The Individual Defendants and Shattuck are the "Shattuck Defendants."

37. Each of the Individual Defendants reviewed and signed the Registration Statement.

38. Defendant Citigroup Global Markets Inc., was an underwriter of the Company's IPO. Citigroup earned approximately $6.3 million from the IPO by selling approximately 5.3 million shares.

39. Defendant Cowen and Company, LLC was an underwriter of the Company's IPO. Cowen earned approximately $5.0 million from the IPO by selling approximately 4.2 million shares.

40. Defendant Evercore Group L.L.C. was an underwriter of the Company's IPO. Evercore earned approximately $4.2 million from the IPO by selling approximately 3.5 million shares.

41. Defendant Needham & Company was an underwriter of the Company's IPO. Needham earned approximately $0.8 million from the IPO by selling approximately 0.7 million shares.

42. Citigroup, Cowen, Evercore, and Needham are the "Underwriter Defendants".

43. The Shattuck Defendants and the Underwriter Defendants are the "Securities Act Defendants."

44. Witness 1 worked for Shattuck from before 2020 through Spring 2021.

45. Witness 2 worked for Takeda's New Product Planning – Immuno-oncology between March 2020 and April 2022. She worked on the commercial program of the Takeda Agreement. Witness 2 was one of the eight-member Takeda PD/OX commercial team.

46. Witness 3 was a Process Development Specialist at Shattuck from April 2019 through April 2021. Witness 3 worked in Shattuck's Durham office, where Shattuck's lab was located. Witness 3 was involved in developing cell lines and other materials necessary to produce Shattuck's fusion proteins.

47. Plaintiffs' expert Stephen Schoenberger is a Professor at the La Jolla Institute for Immunology and an adjunct professor at the division of hematology and oncology at the Moores Cancer Center at UC San Diego Health. He is the director of translational science at the San Diego Center for Precision Immunotherapy. Between July 2015 through November 2017, he served as the Head of Cancer Vaccines at Human Longevity, Inc., a company founded by the team that first sequenced the human genome. He specializes in translational cellular therapies. He has expertise in clinical trials.

IV. SHATTUCK RAISES $232.3 MILLION IN ITS IPO

48. On September 18, 2021, Shattuck filed a Registration Statement on Form S-1. After amendments on October 5 and October 8, the Registration Statement was declared effective on October 8, 2021.

49. Pursuant to the Registration Statement, on October 13, 2021, Shattuck sold 13,664,704 (including underwriters' overallotment) at $17.00 per share for gross proceeds of $232.3 million. Before its IPO, Shattuck had raised or earned a total of only $239.1 million.

V. DEFENDANTS' MISLEADING OMISSOINS

A. Immuno-oncology Treatments Flourish in the 2010s

50. The immune system protects the body from pathogens. But an excessive immune response has its perils, too. To ensure the response is neither too strong nor too weak, the immune system uses two types of protein to initiate and amplify, or dampen and eliminate, the response.

51. The first type of protein stimulates the creation of the T cells that begin the adaptive immune system's response to potentially harmful antigens, including cancer cells.[1] OX40 is one such protein.

52. The second type of protein prevents immune system cells from destroying antigens, thus dampening the immune response. For example, PD-L1 proteins on immune system cells bind to receptors on antigens called PD-L1. The binding prevents the T cell from recognizing its antigen and destroying the target cell, as shown in Figure 1 below. One of the things that makes cancer cells is that they co-opt immune checkpoint-mediated physiological mechanisms to avoid detection and destruction by T cells, including by expressing too many of the dampening proteins, especially PD-L1, the receptor that binds to PD-1.

[1] An antigen is by definition any substance that causes a specific immune response against it by B or T cells.

53. During the 2010s, the FDA approved almost 100 immunotherapies treatments. An outright majority of these treatments work by inhibiting the PD-1/PDL-1 checkpoint. These treatments flood the body with proteins that bind either to the PD-1 proteins on the immune system cells or PD-L1 receptors on cancerous cells (i.e., they "blockade" the PD-1 or PD-L1 proteins). By turning off the immune system's off switch, PD-1/PD-L1 treatments boost the immune response.

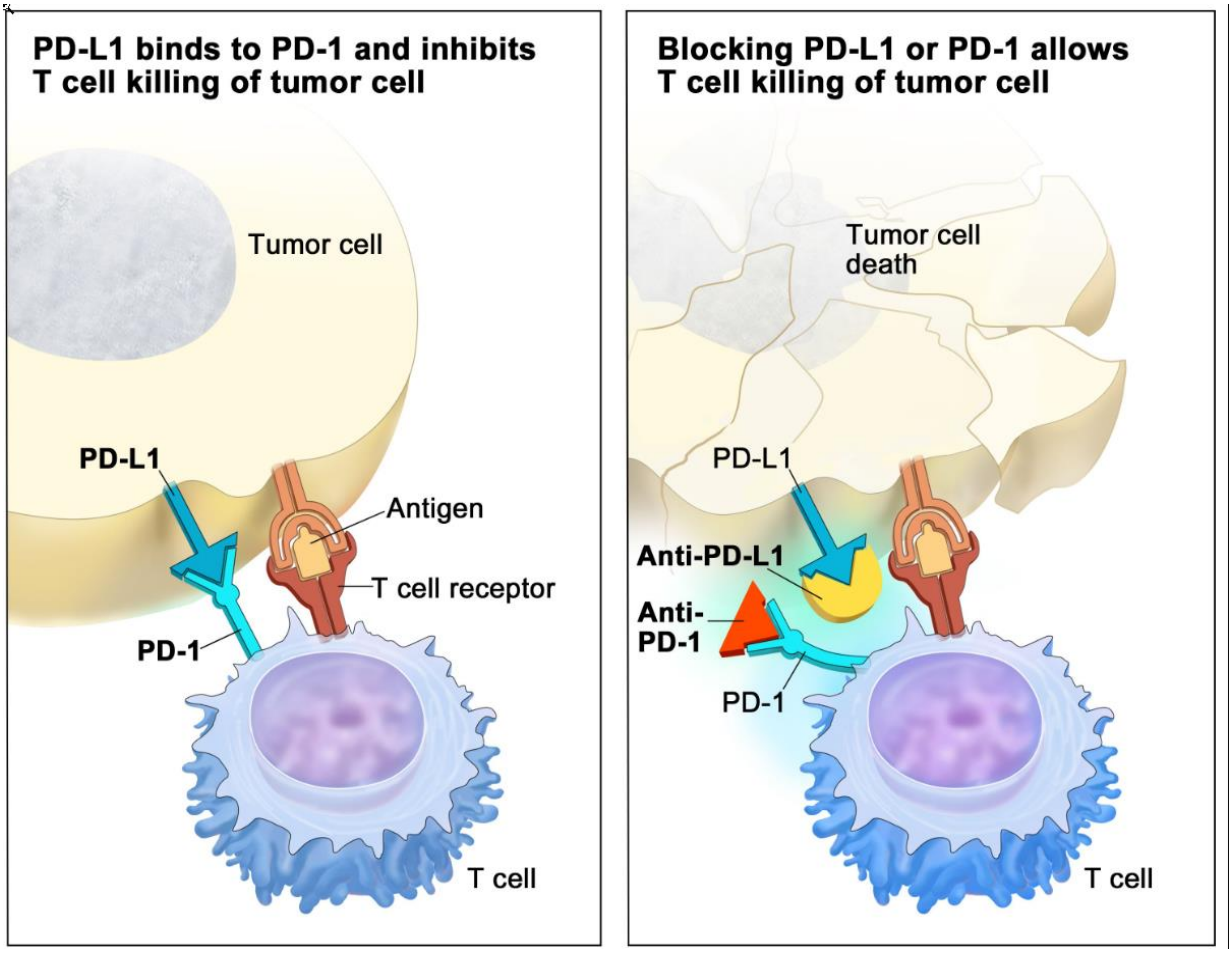

FIGURE 1[2]

[2] Image available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immune-checkpoint-inhibitor .

54. Other treatments, though there are fewer, bind to the molecules that ***de***-activate the ***on*** switches. By filling up the receptors on these molecules, the immunotherapy prevents the molecule from turning off the on switch. Neutralizing these molecules boosts the immune system response. Because treatments that inhibit a response are called antagonists, the treatments that turn on the on switches are called agonists.

B. Shattuck Claims Its Fusion Proteins Improve on Single Protein Immunotherapies

55. Shattuck develops immunotherapies that employ its proprietary ARC platform to create fusion genes. The ARC platform was developed by researchers at the University of Miami and sublicensed to Shattuck.

56. Fusion genes are developed by joining genes that originally coded for separate proteins. Fusion genes code for fusion proteins, which have properties derived from each of the original genes.

57. Functional fusion proteins are almost entirely human-made. When fusion proteins appear naturally, it is usually in a cancer.

58. The ARC platform consists of two proteins fused together to boost immune system responses. One of the proteins enhances the effects of a receptor or molecule that increases immune system response, like OX40. The other protein dampens the effect of a receptor or molecule that inhibits immune system response, like PD-1. The ARC platform can be used with a wide range of proteins.

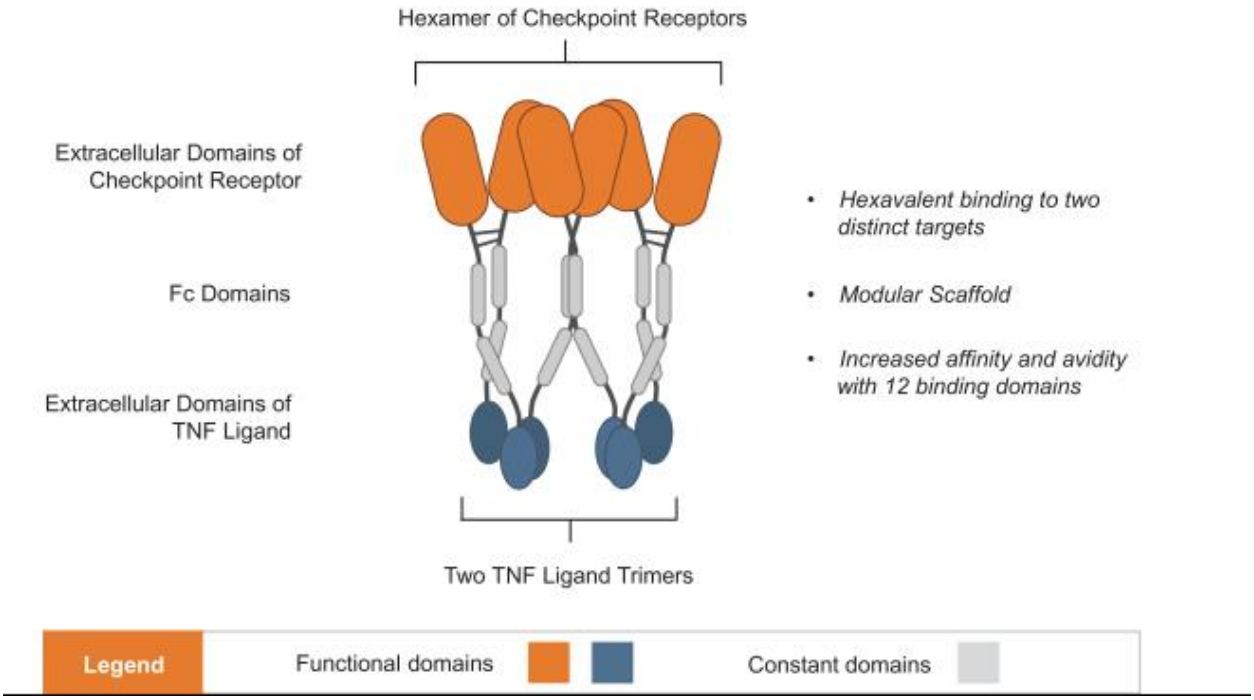

FIGURE 2

59. Patients can be treated with an infusion that contains both PD-1 blockers and OX40 stimulators, which is easier and safer than using a complex synthetic protein like PD/OX. But Shattuck maintains that PD/OX is superior because PD/OX purportedly converts an inhibitory PD-1/PD-L1 signal into an activating signal.

C. Shattuck Signs a Transformative Agreement with Takeda to Develop PD/OX

60. Shattuck Labs was founded in May 2016.

61. In August 2017, Shattuck entered into a transformative agreement with Takeda Pharmaceuticals, Inc.

62. The Takeda Agreement provided for the development and Phase I clinical trials of two fusion proteins, one of which is PD/OX ("Takeda Proteins").[3]

[3] The Takeda Agreement also provided for the development of two other much less advanced fusion proteins.

63. The Takeda Agreement, which was attached as an exhibit to the Registration Statement, assigned to Shattuck the responsibility of conducting these clinical trials. Takeda's responsibility was to pay milestone payments to Shattuck and reimburse it for most of the clinical trial costs.

64. In exchange, the Takeda Agreement granted Takeda an option to license either of the Takeda Proteins up to and after their Phase I clinical trials for an upfront and percentage fee.

65. Takeda is a multinational company with tens of billions of dollars in revenues. It has taken dozens of products through FDA clinical trials. Its wholly-owned subsidiary Millennium Pharmaceuticals Inc. (d/b/a Takeda Oncology), Shattuck's counterparty in the Takeda Agreement, was founded in 1993 and has more than 1,000 employees. In the year ended March 31, 2018, Takeda's oncology drugs earned more than $3.2 billion (¥356 billion). Takeda also has significant experience developing and manufacturing biologics-based immunotherapies like PD/OX.

66. The Takeda Agreement benefited Shattuck in three ways. First, financial: by the time of the IPO, Takeda had paid Shattuck $75.7 million in milestone payments and expense reimbursements, or about a third of all funds Shattuck had raised as of that time. Second, credibility: Takeda's purported seal of approval allowed Shattuck to raise money from other investors. Third, know-how: Shattuck is a small company that has never completed any clinical trial, and Takeda's assistance is critical to Shattuck's ability to manufacture and test its products.

D. Shattuck Conducts the Clinical Trial

i. Phase I Cancer Treatments Are Conducted with An Eye Towards Pivotal Phase II Trials

67. The purpose of cancer treatments is to provide better clinical outcomes to patients, such as greater longevity. But clinical outcomes are difficult to measure. Among other things, many cancers progress slowly. Thus, cancer treatments are commonly evaluated through their

impact on tumor size and growth, which are called surrogate endpoints. The Response Evaluation Criteria in Solid Tumors ("RECIST") are the clinical guidelines employed to evaluate progression on the surrogate endpoints. The iteration of RECIST criteria that applies to immunotherapy, called iRECIST, standardizes measurements of the tumor's response to the treatment. The metrics include:

a. Complete response (iCR): the disappearance of target and non-target lesions and normalization of tumor markers.

b. Partial Response (iPR): at least 30% decrease in tumor size.

c. Confirmed Progressive Disease (iCPD): at least 20% increase in tumor size confirmed by either further increase in size or new lesions or progression in lesion categories at later scans.

d. Unconfirmed Progressive Disease (iUPD): at least 20% increase in tumor size, but without confirmation set out in the earlier subparagraph c.

e. Stable Disease (iSD): decrease in tumor size of less than 30% or increase of less than 20%.

68. Most drugs and biologics are approved after at least three clinical trials. In the classic case, Phase I trials establish that a drug is safe while Phase II trials are exploratory: they establish the parameters (such as dosage and dosing schedules) under which the product will face its pivotal Phase III trials.

69. Nearly half of cancer treatments are approved after only two clinical trials based on the FDA's Accelerated Approval program. The Accelerated Approval program is meant to accelerate the development of treatments for serious diseases that improve on existing therapies. At Phase II, the new drug or biologic is tested against existing treatments; if the new drug or

biologic provides a meaningful therapeutic benefit over available therapies, the sponsor will submit the drug or biologic for approval without conducting Phase III trials. Thus, for cancer treatments, Phase II rather than Phase III trials are often pivotal. As of January 2021, 151 oncology treatments had received Accelerated Approvals, including 35 treatments that targeted the PD-1/PD-L1 off switch, or almost half.[4]

70. As a result, cancer treatments' Phase I trials must also perform many of the same functions that are typically left to Phase II trials. In particular, they must show not only that the product is safe but also preliminarily show efficacy and establish the precise treatment conditions the sponsor will employ in pivotal trials.

ii. Shattuck Designs the Clinical Trial to Test PD/OX's Safety and Efficacy

71. Shattuck began recruiting for the PD/OX clinical trial ("Clinical Trial") in May 2019.

72. As set out in Figure 3 below, which appears on the poster Shattuck presented at an annual Society for Immunotherapy of Cancer ("SITC") convention on November 11, 2021 ("Poster"), the Clinical Trial was a dose escalation study. Dose escalation studies are useful when the treatments have never been tested on human beings. The dose escalation study begins with the investigators treating patients with the lowest dose level. Once a pre-determined number of patients have been treated and enough time has passed to ensure there are no serious side effects that show the treatment is unsafe, the investigators move on to the next dose level. The investigators continue to escalate doses until they reach the highest planned dose level or side effects appear that show the treatment is unsafe at a given dose level.

[4] Julia Beaver, Accelerated Approval for Oncology Drug Products: Regulatory Overview, April 27, 2021, slides 7 & 10, available at https://www.fda.gov/media/147925/download .

73. Immunotherapy works by releasing the brakes on the immune system. It is well understood that immunotherapies may have toxic side effects. These side effects' profile and severity vary by type of immunotherapy. Functional fusion proteins do not regularly appear in nature and have not previously been tested, so the FDA was concerned about PD/OX toxicity.

74. To overcome the FDA's concern that patients in the Clinical Trial would be exposed to dangerous levels of toxicity, Shattuck agreed to include a series of cohorts that received tiny doses. These patients received doses of 0.1mg/kg to as little as 0.0001mg/kg. These doses were not expected to have any therapeutic effect. Their sole purpose was to ensure that patients would not be harmed by higher, therapeutic doses. 10 patients received these subtherapeutic doses. The potentially therapeutic doses Shattuck was analyzing were 0.3 mg/kg, 1.0mg/kg, 3.0mg/kg, and 6.0mg/kg. The clinical trial design is illustrated in Figure 3:

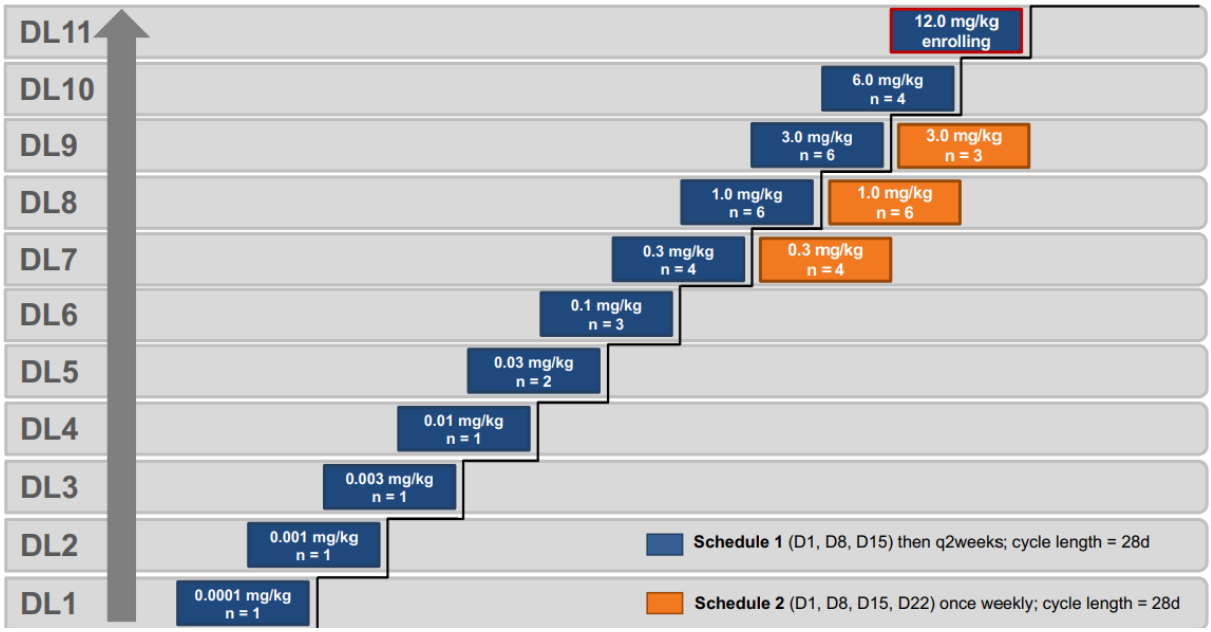

FIGURE 3

75. Patients received intravenous PD/OX infusions on Days 1, 8, and 15 of the Clinical Trial, and every two weeks thereafter until the patient left the trial. Patients were scanned every eight weeks at a minimum to measure tumor size.

76. Patients could have received, and 58% of patients did receive, prior immunotherapies. But patients whose cancers had progressed within 3 months of the beginning of any previous immunotherapy were excluded from the study. Thus, only patients who had actually responded to previous immunotherapies were included in this 58% group. The remaining 42% were patients with cancers known to respond to PD-1 but who were in jurisdictions where, for whatever reason, PD-1 treatments were not part of the standard of care.

77. Patients would continue on the trial until: (a) the patient developed unacceptable side effects; (b) the patient withdrew consent, though only one patient did so in the initial dose escalation study; or (c) the patient's cancer progressed.

78. Once the initial dose escalation study was completed, Shattuck would expand the study with one or more additional cohorts ("Expansion Cohorts"). As set forth in Figure 3, each Expansion Cohort's dose level would be set at one of the levels studied in the initial dose escalation study. The Expansion Cohorts would follow the same principles as the initial dose escalation study; patients would be recruited into a cohort until the cohort filled out, then new patients would be recruited into the next cohort, and so on.

79. The Clinical Trial's primary aim was to determine whether and at what doses PD/OX is safe. But because Shattuck expected that Phase II would be the pivotal trial, the efficacy-related secondary outcomes were also critical. The principal secondary endpoints were:

a. The proportion of patients who achieved either a complete response or a partial response, as measured by iRECIST ("Response Endpoint"); and

b. The proportion of patients who achieved stable disease for at least 12 weeks, as measured by iRECIST ("Stable Disease Endpoint").

iii. Shattuck Learned of Developments in the Clinical Trial in Real Time

80. Most clinical trials are placebo-controlled and double-blinded. But the Clinical Trial was open label. All patients received PD/OX; there was no group that received placebos. As a result, all investigators and patients knew they were receiving PD/OX and the dose thereof.

81. Because the Clinical Trial was open label, Shattuck was not blinded to the data.

82. Shattuck had real-time access to clinical trial results. As set out above, Shattuck modeled its practices on Takeda. According to Witness 2, when Takeda conducted an open-label clinical trial, it was informed of patient withdrawal either on the day of the withdrawal day or the next day. Indeed, according to Schoenberger, the deadline for investigators to report data to the sponsor is rarely more than a week.

83. Moreover, FDA regulations require that the sponsor determine whether any negative clinical development is related to the treatment, with these events called "adverse reactions". 21 C.F.R. §312.32(a). If the patient dies and the sponsor determines that the death is an adverse reaction to the treatment, the sponsor must report it to the FDA within 7 calendar days. *Id.* at (c)(1)(2). Investigators notify sponsors of deaths well in advance of the 7 calendar-day deadline so the sponsors can determine whether the death is a reportable adverse reaction.

84. According to Schoenberger, in an open-label clinical trial, data from patient withdrawals and scans should be promptly entered into a database. Instances in which sponsors access the study database are typically logged.

85. Shattuck either maintained the PD/OX database itself ("Database") or had unlimited real-time access to it.

86. Using the Database, Shattuck could create comprehensive reports on the Clinical Trial's progress. These reports would have informed Shattuck's management of how each patient had fared or was faring, including the date of every scan, RECIST diagnoses at each of these scans, the date of patients' withdrawal and the reasons therefor, and whether the patient remained in the trial. Because the PD/OX Clinical Trial was Shattuck's most advanced and was critical to the Takeda Agreement, Shattuck's personnel, including its Chief Medical Officer, would have frequently accessed the Database to keep abreast of developments, or were negligent in failing to do so.

87. According to Schoenberger, when investigators communicate patients' withdrawal, they also communicate whether this is due to likely progression by iRECIST criteria. In addition, this information is communicated within a week of the patient's scan.

iv. The Clinical Trial Shows PD/OX Doesn't Work

88. In total, 30 patients[5] were enrolled in the initial portion of the Clinical Trial, as shown by Figure 4.

89. The last remaining untreated patient is the one who appears at the very top of Figure 4. That is because the Poster reports data as of June 11, 2021, and Figure 4 shows the patient had been receiving PD/OX for about 28 weeks, meaning that the patient began treatment in late November 2020, after the October 13, 2020, IPO.

90. ***No*** patient achieved a durable complete response. One patient, dosed at 1.0mg/kg, achieved a temporary partial response, thus meeting the Response Endpoint. The partial response only lasted for 24 weeks. Shortly after that response, the patient's cancer progressed and the patient left the trial.

[5] Figure 3, drawn from the Poster, incorrectly reports that only 9 patients received non-therapeutic doses. The true numbers are set out in Figure 4, which also appeared in the Poster.

91. A greater proportion who received ***subtherapeutic*** response met the Stable Disease Endpoint than patients who received a ***therapeutic*** dose:

	Number of patients meeting Stable Disease Endpoint	Number of patients treated	Percentage of patients meeting Stable Disease Endpoint
Subtherapeutic	***3***	***10***	***30.0%***
0.3mg/kg	0	4	0%
1.0mg/kg	2	6	33.3%
3.0mg/kg	1	6	16.7%
6.0mg/kg	0	3	0%
Total therapeutic	***3***	***19***	***15.8%***[6]

92. The poor results for patients who received 6mg/kg were particularly concerning. Not every treatment is more effective the higher the dose. Some treatments exhibit a so-called bell-shaped response, where increasing dosage beyond some point of maximum efficacy actually reduces the treatment's efficacy. Some studies have shown that certain OX40 stimulating drugs have a bell-shaped response.[7] Yet there was no reason to suspect the Clinical Trial failed because the dose was insufficient. As of September 9, 2020, at the latest, 3 of 4 planned patients had been treated with a 6.0mg/kg dose. All withdrew because of disease progression, one at two weeks, another at four weeks, and the third at eight weeks. Moreover, the only group that saw better results than the non-therapeutic patients were those who received 1.0mg/kg, suggesting that increasing doses would not solve the problem. Thus, if anything, higher doses caused poorer outcomes.

[6] Excludes the patient who began treatment after the IPO.

[7] E.g. Emily Rowell et al, INBRX-106: a novel hexavalent anti-OX40 agonist for the treatment of solid tumors (J. for ImmunoTherapy of Cancer Vol. 9, Issue Suppl. 2, available at https://jitc.bmj.com/content/9/Suppl_2/A897).

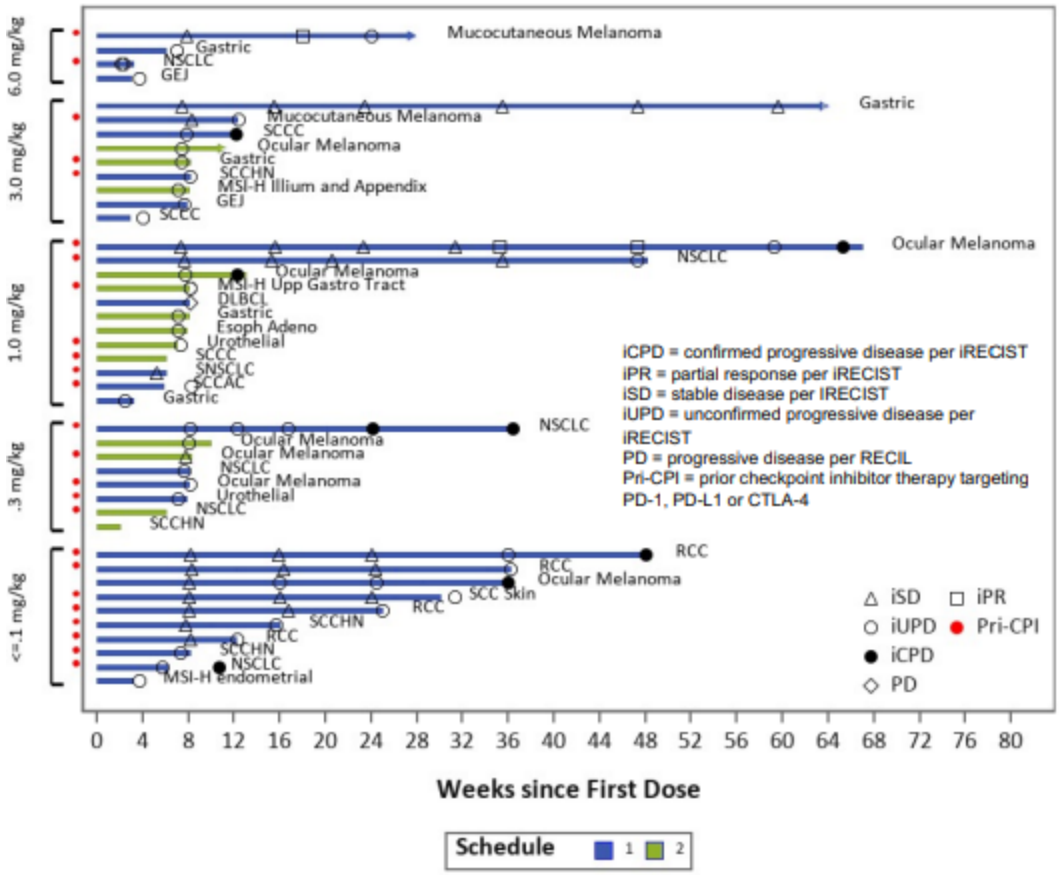

FIGURE 4

93. The outcomes came in before the IPO. Figure 4 shows each patient's duration of treatment. Blue lines show patients treated in the dose escalation study. If a patient's blue line ends with an arrow, then that patient was still undergoing treatment as of June 2021. If not, then the patient discontinued treatment after the number of weeks set out in the chart

94. Shattuck had substantially completed recruitment by April 2020.

95. First, when Witness 2 started work on the PD/OX project in April 2020, around 30 patients had been recruited, or substantially all. Further, by April 2020, discussions of the Expansion Cohorts were already ongoing. Thus, even then, the Clinical Trial had already produced substantial results.

96. Second, the Takeda Agreement established a Joint Development Committee ("JDC"). Takeda and Shattuck had an equal number of seats on the JDC.

97. The JDC was the method through which Shattuck kept Takeda informed of developments in the PD/OX clinical trials. Takeda Agreement, Article 2.2.

98. According to Witness 2, the JDC met approximately every six months. Before each meeting, Shattuck would circulate detailed presentations, including the results obtained to date.

99. According to Witness 2, the JDC held a meeting in June or July 2020. By the time of that meeting, Shattuck was "wrapping up" the initial dose escalation study and designing Expansion Cohorts. Shattuck had shut down recruitment between March and June 2020 because of COVID, so all the patients discussed at the June or July 2020 meeting would have been recruited in or before March 2020.

100. Third, according to the Registration Statement, as of September 9, 2020, 29 patients had received treatment with PD/OX. [8]

101. It is plausible that Shattuck would recruit no patients, or at most one or two, between June and September 2020. PD/OX is an immunotherapy; by entering treatment during COVID, patients bore the risk that they would catch COVID at the hospital where they received infusions and the risk that COVID would be more dangerous because PD/OX altered their immune response. The five Clinical Trial sites were located in: Barcelona, Spain; Toronto, Canada; Leuven, Belgium; Houston, Texas; and Nashville Tennessee. In July 2020, there were COVID resurgences in both Barcelona and Belgium, and Texas Governor Abbott ordered a halt to elective surgeries in

[8] Because Witness 2 does not report that Shattuck had recruited exactly 30 patients by April 2020, the witness's statement is consistent with Shattuck's statement that it had recruited exactly 29 patients by September 9, 2020.

the area around Houston. Tennessee was under a state of emergency from March through October 2020.

102. There were 23 weeks between the end of April 2020 and Shattuck's IPO. Based on the above, when the Registration Statement was declared effective, there were at most four patients receiving therapeutic doses whose treatment was ongoing. Of these, one had experienced disease progression since the beginning of the trial. It was also clear that patients on therapeutic doses had done significantly worse on the Stable Disease Endpoint than patients on subtherapeutic doses.

103. Shattuck planned that after completing the initial dose escalation study, it would recruit more patients to test potentially promising dose levels. As set out in Figure 3 above, these expansion cohorts were set up "at a dose range where immunologic activity was being observed." According to Witness 2, discussions were ongoing as of the June or July 2020 JDC meeting. The expansion cohorts were dosed at 0.3mg/kg, 1.0mg/kg, and 3.0mg/kg—but not 6.0mg/kg, the highest dose.

104. Before the IPO, 3 Shattuck employees involved in the PD/OX Clinical Trial told Witness 3 that the Clinical Trial data showed that PD/OX was not effective.

105. In late 2019 or early 2020 (pre-COVID), Witness 3 spoke with Hannah McKay, a Shattuck Clinical Research Scientist who worked on the PD/OX Clinical Trial. Ms. McKay told Witness 3 that recruitment for the Clinical Trial was not going as planned. In particular, she found it nearly impossible to fill out one particular cohort. Ms. McKay explained that Shattuck's recruiting problems stemmed from the fact that, as the data was showing, PD/OX was not effective.

106. Shattuck's public filings confirm Ms. McKay's account. Clinical trials, along with basic descriptions thereof, must be pre-registered with the government and are available at

www.clinicaltrials.gov. According to these filings, Shattuck originally planned to recruit 87 patients in the Clinical Trial (including Expansion Cohorts). Yet it only recruited 43.

107. Witness 3 also discussed the PD/OX Clinical Trial with Sudie Rowshan, a Shattuck Director of Project Management, likewise in late 2019 or pre-COVID 2020. Ms. Rowshan told Witness 3 that even then, she had developed doubts about whether PD/OX worked because of the Clinical Trial. Rowshan also acknowledged that Shattuck having difficulty recruiting patients. Witness 3 discussed the PD/OX Clinical Trial with a third member of the trial team, who made the same points. Indeed, according to Witness 3, "we all theorized" that PD/OX did not work, citing his conversations with McKay, Rowshan, and the third member of the Clinical Trial team.

108. As of October 1, 2020, Shattuck had 50 full-time employees. While Shattuck had a small 4,550 square foot office in Austin, Texas, it ran most of its operations, including all its research and development, from its 32,23-foot office at 21 Alexandria Way, Suite 200, Durham, North Carolina

109. Witness 1 worked in Shattuck's Durham office. During most of Witness 1's tenure, Shattuck's Durham office occupied a single floor and had an open office plan. Schreiber had a desk in Shattuck's Durham office.

E. PD/OX'S POOR CLINICAL TRIAL RESULTS WERE REQUIRED TO BE DISCLOSED IN THE REGISTRATION STATEMENT

i. The Registration Statement Omitted to State a Material Fact Necessary to Make the Statements Therein Not Misleading

110. Defendants explained in the Registration Statement that "[a]ntibodies targeting OX40 have not demonstrated sufficient efficacy in clinical trials". Defendants claimed that PD/OX had the "potential" to address these deficiencies through "a differentiated approach to targeting PD-1 and OX40, as compared to existing antibody therapies, either as individual monotherapies

or in combination." PD/OX's "properties are intended to replace PD-L1-mediated immune inhibition with OX40 costimulation to synergistically enhance anti-tumor response."

111. In the Registration Statement, Defendants claimed that in preclinical work, PD/OX had shown that it stimulated the immune system: these preclinical trials "provide evidence of on-target biology driven by ARC compound-mediated stimulation of [] OX40." Defendants linked the stimulation of the immune system to anti-tumor activity: "In preclinical studies, [PD/OX] was found to be a highly potent stimulator of an adaptive immune response, and also demonstrated greater anti-tumor activity than anti-PD-1 antibodies or OX40-agonist antibodies, either alone or in combination."

112. Defendants claimed in the Registration Statement that the PD/OX Clinical Trial had shown that PD/OX stimulated an immune response:

> Preliminary pharmacodynamic activity has also been evaluated in 22 patients treated across a dose-range of 0.0001 to 3 mg/kg. Post-dose receptor occupancy on OX40-positive lymphocytes was observed in a dose-dependent fashion, and the total number of OX40-positive cells in the blood declined rapidly post-infusion of [PD/OX]. We believe the post-infusion decreases in OX40-positive lymphocytes provides evidence of on-target biology. In NHP [non-human primates], similar post-infusion decreases in lymphocytes were associated with migration of lymphocytes into tissues.

113. Defendants also represented in an underwriting agreement incorporated by reference into the Registration Statement that:

> The descriptions in the Registration Statement, the Disclosure Package and the Prospectus of the results of any Company Trials are accurate and complete descriptions in all material respects and fairly present the data derived therefrom.

114. By highlighting the link between preclinical efficacy and immune system stimulation, stating that the Phase I trial had achieved immune system stimulation, but not disclosing that the Phase I trial had shown lack of efficacy, Defendants negligently gave the misleading impression that the Phase I trial was showing efficacy. Defendants reinforced the misleading impression by standing for that the Registration Statements' discussion of the trials

was "accurate and complete". To prevent their statements from being misleading, Defendants were required to disclose, but did not, that the nearly-complete PD/OX Clinical Trial was showing a lack of efficacy.

ii. Item 303 of Regulation S-K Required Disclosure that the PD/OX Clinical Trial Showed a Lack of Efficacy

115. SEC Regulation S-K (27 C.F.R. § 229.10) mandates that registration statements such as the ones filed by Shattuck comply with the other requirements of Regulation S-K "to the extent provided in the forms to be used for registration under the [Securities] Act." 17 C.F.R. § 229.10.

116. Form S-1 mandates disclosure of the information required by Item 303.

117. Item 303 of Regulation S-K requires the issuer to discuss known trends, uncertainties, and events. The Disclosure should appear in the section of an issuer's registration statement reporting "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A"). In a 1989 Interpretive Release, the SEC described the purposes of MD&A:

> The Commission has long recognized the need for a narrative explanation of the financial statements, because a numerical presentation and brief accompanying footnotes alone may be insufficient for an investor to judge the quality of earnings and the likelihood that past performance is indicative of future performance. MD&A is intended to give investors an opportunity to look at the registrant through the eyes of management by providing a historical and prospective analysis of the registrant's financial condition and results of operations, with a particular emphasis on the registrant's prospects for the future.

Management's Discussion & Analysis of Fin. Condition & Results of Operations; Certain Inv. Co. Disclosures, Release No. 6835 (May 18, 1989) ("1989 Interpretive Release") available at 1989 WL 1092885.

118. Issuers must disclose both (a) known trends and uncertainties and (b) any material impact of known trends and uncertainties on their own operations even if the trends are a matter

of public knowledge. 1989 Interpretive Release, 1989 WL 1092885 at *6. *See also Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 721 (2d Cir. 2011).

119. Item 303 demands disclosure of known trends unless management determines that a material effect on financial condition or results of operations is not likely to appear. The 1989 Interpretive Release provides the following test to determine if disclosure under Item 303 is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:
> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required. (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results is not reasonably likely to occur.
> 1989 Interpretive Release, 1989 WL 1092885, at *6

120. The instructions to Item 303 requires that discussion "shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

121. The Takeda Agreement was critical to Shattuck's past financial operating performance.

122. The Takeda Agreement entitled Shattuck to milestones and reimbursement of expenses.

123. As of the IPO, Shattuck had earned $75.7 million from the Takeda Agreement. Not only was the Takeda Agreement Shattuck's sole source of revenues, it accounted for about a third of the $239.1 million Shattuck had earned or raised from all sources before the IPO.

124. The Takeda Agreement promised substantially more revenues in the future. If Takeda licensed the two remaining Takeda Proteins, Shattuck would be entitled to up to an aggregate of $450 million in clinical, regulatory, and sales milestone payments, up to $78.75 million in upfront license fees, and royalty payments ranging from "high single digits to sub-teens".

125. Although the Takeda Agreement provided for the development of two molecules, the most advanced and valuable of these, by far, was PD/OX. Witness 2 learned in June or July 2020 that Shattuck had already delayed delivering the other molecule by more than a year, and Shattuck was nowhere near ready for clinical trials, so Takeda had no interest in that molecule. In fact, Shattuck has not launched clinical trials on that molecule to this day. According to Witness 2, Shattuck recognized that Takeda was not interested, as the other molecule was not discussed at JDC meetings.

126. The failure of the PD/OX Clinical Trial imperiled the Takeda Agreement itself. Because the Takeda Agreement covered only two molecules, should the Clinical Trial fail to show efficacy, Takeda might simply cancel the agreement altogether.

127. Takeda was bound to fund most of the costs of PD/OX's Clinical Trial but had no obligation beyond that.

128. If the Takeda Agreement were cancelled, Shattuck would lose all of its revenues.

129. Under Item 303, Defendants had an obligation to disclose and discuss that the PD/OX Clinical Trial was showing a lack of efficacy because it was a known trend or uncertainty that could "cause reported financial information not to be necessarily indicative of future operating results or of future financial condition." Defendants negligently failed to do so.

iii. Item 105 Required Disclosure that the PD/OX Clinical Trial Was Showing a Lack of Efficacy

130. Form S-1 mandates disclosure of the information required by Item 105.

131. Item 105 (former Item 503) requires disclosure and discussion of, among other things, "the material factors that make an investment in the registrant or offering speculative or risky." It also requires the issuer to "concisely explain how each risk affects the registrant or the securities being offered." It "discourages" the "presentation of risks that could apply generically to any registrant."

132. Before 2019, the instructions to Item 105 had presented examples of disclosures. However, that year, the SEC amended Item 105 to remove these examples to ensure "registrations [] provide risk disclosure[s] that [are] more precisely calibrated to their particular circumstances."

133. That the PD/OX Clinical Trial was showing a lack of efficacy was one of the most "material factors that make an investment in [Shattuck] speculative or risky." Yet the Registration Statement's disclosure is an extended discussion of the ways clinical trials might theoretically go wrong that is true of literally every company that runs them:

> ***Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.***
>
> To obtain the requisite regulatory approvals to market and sell any of our product candidates and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.
>
> Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency. Prior to obtaining approval to commercialize our product candidates and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must

demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

134. The Registration Statement was misleading for not disclosing and discussing that the Clinical Trial was showing a lack of efficacy.

F. Additional Facts Probative of Underwriter Defendants' Liability

135. In addition, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement under the Securities Act because of the following:

(a) The Underwriter Defendants are investment banking houses that specialize in, among other things, underwriting public offerings of securities. They served as the underwriters of the IPO and shared substantial fees from the IPO collectively.

(b) The Underwriter Defendants also obtained an agreement from Shattuck that it would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws.

(c) Representatives of the Underwriter Defendants also assisted Shattuck and its management and directors in planning the IPO, and purportedly conducted an adequate and reasonable investigation into the business and operations of the Company, an undertaking known as a "due diligence" investigation. The Underwriters had to conduct such due diligence to engage in the IPO. During the course of such investigation, the Underwriter Defendants had continual access to internal, confidential, and current corporate information concerning Shattuck's most up-to-date operational and financial results and prospects. For example, the Underwriter Defendants had access to the Database containing patient results of the PD/OX Clinical Trial. The Underwriters also had the ability to demand that Shattuck provide them with results of the ongoing PD/OX Clinical Trial.

(d) In addition to availing themselves of virtually unlimited access to internal corporate documents, agents of the Underwriter Defendants met with Shattuck's lawyers, management, and top executives and engaged in drafting sessions. During these sessions, Shattuck and the Underwriter Defendants reached an understanding on: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Shattuck's securities would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Shattuck would be made in the Registration Statement; and (v) what responses would be

made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Shattuck's management and top executives, the Underwriter Defendants in the exercise of reasonable care should have known of Shattuck's existing problems as detailed herein.

136. The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with the offers and sales of securities registered thereby, including those to Plaintiffs and the other members of the Class.

VI. PLAINTIFFS' CLASS ACTION ALLEGATIONS

137. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and the Class defined in ¶1 herein.[9]

138. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class Members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe there are thousands of Class Members. Record owners and other Class Members may be identified from records maintained by Shattuck, its transfer agent, or nominees, and may be notified of the pendency of this action using the form of notice similar to that customarily used in securities class actions.

139. Plaintiffs' claims are typical of the claims of Class Members, as all Class Members are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

[9] Excluded from the Class are: (a) persons who suffered no compensable losses; (b) Defendants, the present and former officers and directors of Shattuck at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which any of the Defendants, or any person excluded under this subsection (b), has or had a majority ownership interest at any time.

140. Plaintiffs will fairly and adequately protect the interests of the Class Members and have retained counsel competent and experienced in class and securities litigation.

141. Common questions of law and fact exist as to all Class Members and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a) whether Defendants violated the federal securities laws;

b) whether the Registration Statement contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and

c) to what extent the Class Members have sustained damages and the proper measure of damages.

142. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class Members may be relatively small, the expense and burden of individual litigation make it impossible for Class Members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

VII. COUNT I

Violations of Section 11 of the Securities Act
Against All Defendants

143. Plaintiffs repeat and re-allege the foregoing allegations. Plaintiffs disclaim any allegations of fraud, recklessness, or intentional misconduct.

144. This Count is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of Class Members who have claims under ¶1.a hereof, against all Defendants.

145. The Registration Statement contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

146. The Defendants were responsible for the contents and dissemination of the Registration Statement; signed the Registration Statement or were underwriters, both of whom are appropriate defendants in this Count.

147. Shattuck is strictly liable to Plaintiffs and such Class Members for the misstatements in and omissions from the Registration Statement.

148. None of the Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

149. The Underwriters owed to the holders of the common stock acquired through the Registration Statement the duty to make a reasonable and diligent investigation of the statements contained in the Registration Statement at the time they became effective to ensure that such statements were true and correct and that there was no omission of material facts required to be stated in order to make the statements contained therein not misleading.

150. Plaintiffs acquired Shattuck common stock pursuant to and traceable to the Registration Statement.

151. At the time of their purchases of Shattuck common stock, Plaintiffs and such Class Members were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein.

152. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Registration Statement that should have been made and/or corrected

through the exercise of reasonable diligence, and within three years of the effective date of the Registration Statement. It is therefore timely.

VIII. COUNT II

Violations of Section 15 of the Securities Act
Against the Individual Defendants

153. Plaintiffs incorporate all the foregoing allegations by reference. Plaintiffs disclaim any allegations of fraud, recklessness, or intentional misconduct.

154. This cause of action is brought pursuant to §15 of the Securities Act, 15 U.S.C. §77o against the Individual Defendants, each of whom was a control person of Shattuck during the relevant period.

155. The Individual Defendants were in positions to control and did control, the false and misleading statements and omissions contained in the Registration Statement.

156. None of the Individual Defendants made reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

157. Plaintiffs and Class Members who have claims under ¶1.a hereof have sustained damages. The value of Shattuck common stock has declined substantially due to the Securities Act violations alleged herein.

158. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Registration Statement that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Registration Statement. It is therefore timely.

VIOLATIONS OF THE EXCHANGE ACT ANTIFRAUD PROVISIONS

IX. DEFENDANTS FRAUDULENTLY CONCEAL WORSENING PD/OX CLINICAL TRIAL DATA AND TAKEDA'S DECISION TO PULL THE PLUG

159. Defendants Schreiber, Neill, and Hornblower, are the "Individual Exchange Act Defendants".

160. The Individual Exchange Act Defendants and Shattuck are the "Exchange Act Defendants".

161. As early as April 2020, six months before the IPO, Takeda had decided to terminate the Takeda Agreement because PD/OX did not work.

162. At first, Takeda tried to express its concerns to Shattuck diplomatically. But rather than curtailing the Clinical Trial, by the end of December 2020, Shattuck was proposing to proceed with the Expansion Cohorts.

163. Takeda confronted Shattuck at the January 2021 meeting. There, Takeda told Shattuck that PD/OX had not shown any efficacy. Takeda also told Shattuck that it was willing to give PD/OX another limited shot, but only if Shattuck limited the Expansion Cohort to patients with lung cancer. Unless Shattuck limited the Expansion Cohort to lung cancer patients and the Expansion Cohorts showed efficacy in lung cancer, Takeda was ***not*** interested and ***would not license PD/OX***. If Shattuck did not accept Takeda's demand, Takeda would fund the Expansion Cohorts, as it was contractually obligated to do, but the Takeda Agreement was, in effect, over. The meeting grew contentious.

164. Shattuck ignored Takeda's concerns and tested PD/OX on a basket of different cancers.

165. Takeda's team only held one or two more monthly meetings, and these were desultory 15-minute affairs. After the last meeting, by April 2021 at the latest, Takeda dissolved the team. The agreement ***was*** over.

166. But Defendants did not advise investors of this. Instead, the three Individual Exchange Act Defendants sold about $14 million worth of their personally-held stock.

167. Even as Defendants sold their stock, the case against PD/OX became even more overwhelming. The Expansion Cohorts proved disastrous. Not a single one of the thirteen patients received any clinical benefit as measured by Shattuck's pre-selected endpoints. Shattuck prepared and submitted an abstract containing all the analyses that showed PD/OX didn't work. But Defendants kept implying to investors that the Clinical Trial results were positive.

168. On November 9, 2021, Shattuck finally announced the Takeda Agreement's termination. That same day, SITC released the poster showing that PD/OX had shown a lack of efficacy in the Clinical Trial. That day, the price of Shattuck's shares to fall from their previous close of $19.04 on November 8 to close at $13.59 on November 9, down $5.45 (28.6%), on heavy volume, damaging investors.

A. At a January 2021 Meeting, Takeda Tells Shattuck It Is Not Interested in PD/OX Because the Clinical Trial Data Shows It Doesn't Work

169. Witness 2 joined Takeda in March 2020.

170. Witness 2 joined the Takeda PD/OX project team only a month later in April 2020, right at the beginning of the COVID pandemic in the U.S.

171. According to Witness 2, even by April 2020, it was "very clear on our side" that Takeda was "unhappy with the drug."

172. Indeed, upon joining the team, Witness 2 was told by his or her boss that he or she should manage the Shattuck project "and shut it down."

173. According to Witness 2, the "efficacy data was [Takeda's] issue" with PD/OX. Even as of April 2020, the results were already "uncompelling" and already showed that PD/OX did "not [have] impactful efficacy".

174. Thus, according to Witness 2, Takeda had been looking to "sever" the agreement while avoiding "legal landmines" when they did.

175. According to Witness 2, at first, Takeda attempted to communicate its lack of interest diplomatically. For example, at the June or July 2020 JDC meeting, Takeda expressed skepticism but did not yet deliver the "hardcore message" that Takeda was not interested at all. While Witness 2 was not privy to such communications, based on her position in the program, she is sure they occurred.

176. Yet according to Witness 2, by the end of 2020, frustrated that Shattuck was ignoring Takeda's diplomatic feedback, Takeda decided to confront Shattuck to leave no doubt of its intentions.

177. According to Witness 2, Takeda and Shattuck held a JDC meeting in January 2021 in part to discuss the Dose Expansion cohorts.

178. According to Witness 2, the confrontation took place at the January 2021 JDC meeting.

179. Witness 2 and the witness's management had been "very involved" in preparing for and attending the January 2021 meeting.

180. Chris Arendt, the head of Takeda's Shattuck program, as did the head of Takeda's business development and alliance management program. Defendant Neill attended the January 2021 JDC meeting. Witness 2 also attended the January 2021 JDC meeting.

181. According to Witness 2, between 10 and 15 Takeda employees attended the meeting, including clinicians. Witness 2 believes there were far more Shattuck employees in attendance.

182. According to Witness 2, before the January 2021 JDC meeting, Shattuck provided materials updating Takeda on current PD/OX Clinical Trial data and anticipated future steps.

183. According to Witness 2, at the meeting, Shattuck told Takeda that it would proceed with the Expansion Cohorts. Takeda opposed the Expansion Cohorts and expressed frustration at Shattuck's decision to proceed with them. Takeda told Shattuck that it had not been "listening to the feedback Takeda had been giving".

184. According to Witness 2, after several rounds of back and forth, the meeting became contentious.

185. At the meeting, Takeda told Shattuck that it was willing to give PD/OX a limited additional chance, on two conditions. First, Shattuck would have to limit the Expansion Cohorts to patients with lung cancer. Lung cancer was a significant indication, while the other indications Shattuck was pursuing were very small. Second, Takeda "wanted up-front efficacy" on lung cancer from the Expansion Cohorts. Indeed, because Takeda "kn[e]w [PD-1] works" in lung cancer, if PD/OX were effective for anything, it should be effective for lung cancer. Takeda was not interested. As Witness 2 put it, Takeda had drawn its "line in the sand": if Shattuck did not show with the Expansion Cohorts that PD/OX was effective in lung cancer, then Takeda was not interested.

186. Takeda also told Shattuck they were not seeing any signal of efficacy in any indication.

187. Shattuck ignored Takeda's demand. Shattuck offered, instead, that PD/OX could work in other, smaller indications. Thus, Shattuck advised that it and Takeda should continue to take a "blanket approach" to find "anything" (i.e., any cancer) on which PD/OX might be effective.

188. Yet whatever its misgivings, Takeda was contractually bound to continue funding PD/OX's Phase I Clinical Trial. Takeda Agreement, at 2.1(a), 5.2(a). Takeda's responsibility included funding the Dose Expansion study. March 2020 Amendment 3 to Takeda Agreement, 2.7. The Takeda Agreement could not be terminated unilaterally unless materially breached by the other party. Takeda Agreement, Article 8.

189. Pursuant to the Takeda Agreement, Shattuck was required to explain its rationale for the Dose Expansion cohorts to Takeda. But if Shattuck and Takeda disagreed, the decision was Shattuck's. March 2020 Amendment 3 to Takeda Agreement, 2.7.

190. Takeda was contractually obligated to fund the Expansion Cohorts. The decision to proceed with the trial, or even at which dose to do so, was up to Shattuck. Takeda expressed its disapproval but Shattuck decided to proceed with the blanket Expansion Cohorts, dragging Takeda along, and knowing that Takeda would not license PD/OX.

191. Thus, after the January 2021 meeting, Schreiber, Hornblower, and Neill knew or were reckless in not knowing that there was no chance Takeda would license PD/OX.

192. Takeda reacted accordingly. According to Witness 2, an internal Takeda Product Development Team ("Takeda Team") met monthly to discuss the collaboration with Shattuck. The Takeda Team only held one or two monthly meetings after the January 2021 JDC meeting. The meeting(s) lasted no more than 15 minutes. Takeda stopped holding these meetings within two or three months of the January 2021 JDC Meeting. At that time, the Takeda Team was dissolved.

B. Defendants Learn All the Information Later Revealed at the Close of the Exchange Act Class Period but Continue Making Misleading Statements

193. Defendants substantially completed the Clinical Trial, except for the Expansion Cohorts, before making the first Exchange Act Class Period statements.

194. The last patient in the dose escalation portion of the Clinical Trial began treatment in or around late November 2020.

195. On February 17, 2021, at the Citi 9th Annual Immuno-oncology Leadership Summit ("February 17 Presentation"), Defendant Schreiber told investors that Shattuck had selected the dose levels for the Expansion Cohorts: 0.3mg/kg, 1.0mg/kg, and 3.0mg/kg—but not 6.0mg/kg.

196. Defendant Schreiber explained during the presentation:

> And we're generating additional data from those three dose levels [0.3 mg/kg, 1.0 mg/kg, and 3.0 mg/kg] based on and then the selection of those dose levels was based on PK [pharmacokinetic] and pharmacodynamic data that ***was telling us that these were the right place to explore further and we expect to nominate the recommended Phase 2 dose out of one of those three dose levels.***

197. Accordingly, by February 17, Shattuck had sufficient data to determine that the 6.0mg/kg dose was not effective and that no higher dose would be.

198. Further, at that time, Shattuck had substantially completed the dose escalation portion of the Clinical Trial and presented results to Takeda. These results had prompted Takeda to express that there was no sign of efficacy.

199. June 11, 2021, was the data cutoff date for the data presented in the Poster. Thus, all of the information presented on the Poster was available to Shattuck as of June 11.

200. As shown in Figure 4, the Expansion Cohort results were even worse than the initial dose escalation portion of the Clinical Trial. Only one of the 13 patients treated was continuing treatment as of June 11. That patient was only 12 weeks into the trial, and the patient's first and

only scan showed progressive disease. All other patients had dropped out of the trial within 8 weeks or fewer.

201. ***No*** patient met the Response Endpoint.

202. ***No*** patient met the Stable Disease Endpoint. Only one patient had a scan that showed stable disease. The scan was taken at 8 weeks. The patient dropped out soon after this one and only scan.

203. In an August 11, 2021, press release, Shattuck reported that it had already submitted an abstract to SITC for its meeting taking place November 10-14, 2021, containing the data presented in the Poster, based on data available as of June 11, 2021. The Poster's authors included four Shattuck employees, one of whom was its Chief Medical Officer.

204. Thus, at the time of the August 11, 2021, press release, Exchange Act Defendants were certainly aware of the data set out in Figure 4.

C. Exchange Act Defendants Sell Stock While Concealing that the PD/OX Trials Had Shown a Lack of Efficacy and that Takeda Had Backet Out

205. In connection with the IPO, insiders including the Individual Exchange Act Defendants entered into a customary 180-day lockup. The lockup prevented them from selling their Shattuck shares until April 13, 2021.

206. Thus, at the time of the January 2021 meeting, the Individual Exchange Act Defendants had not sold and could not sell any shares.

207. The poor clinical trial results, Takeda's withdrawal, and the reason therefor were obviously negative material non-public information. If this news were disclosed, Shattuck's stock price would fall. The Individual Exchange Act Defendants would not be able to sell shares to the public at all or would have to sell their shares at much lower prices.

208. Thus, the Individual Exchange Act Defendants had a motive to conceal Takeda's withdrawal and the reasons therefor.

209. The Individual Exchange Act Defendants had a duty to either abstain from selling shares or to disclose the material nonpublic information in their possession.

210. Yet once the lockup expired, Neill, Schreiber, and Hornblower each sold personally-held shares for net proceeds of $1.6 million, $2.5 million, and $9.3 million, respectively, while in possession of material non-public information.

211. Defendant Neill started the Class Period with 88,466 shares. During the Class Period, he sold 50,000 shares for proceeds (net of costs of exercising options) of $1,589,616.20:

Type of transaction	Date	Shares sold (received)	Price	Total proceeds
Exercise of stock option	November 5, 2020	(2,211)	$0.01	($22.11)
Exercise of stock option	December 22, 2020	(4,426)	$0.01	($44.26)
Open Market Sale	April 15, 2021	24,000	$30.74	$737,760.00
Open Market Sale	April 28, 2021	20,000	$35.00	$700,000.00
Exercise of stock option	May 12, 2021	(8,860)	$0.01	($88.60)
Open Market Sale	May 17, 2021	2,000	$26.27	$52,542.40
Open Market Sale	June 15, 2021	2,000	$27.53	$55,050.60
Open Market Sale	July 15, 2021	2,000	$22.13	$44,263.20
Exercise of stock options	August 10, 2021	(2,203)	$0.01	($22.03)
Total sales	**50,000**			
Total net sales	**32,300**			
Net proceeds	**$1,589,616.20**			

212. Between November 9, 2021, and the filing of this Complaint, Neill increased his holdings by 53,325 shares, consisting of 20,000 obtained by exercising stock options on November 11, 2021, and an award of 33,325 shares of common stock on January 10, 2022. He also received options to purchase 66,640 shares on January 10, 2022. In that time, Neill has not sold a single share.

213. Defendant Schreiber began the Class Period with 2,711,024 shares. During the Class Period, he sold 95,000 shares for total proceeds (net of costs of exercising options) of $2,496,018.21:

Type of transaction	Date	Shares sold (received)	Price	Total proceeds
Open Market Sale	May 10, 2021	8,188	$26.9845	$220,949.09
Open Market Sale	May 11, 2021	14,783	$28.0282	$414,340.88
Open Market Sale	May 12, 2021	14,242	$27.2881	$388,637.12
Open Market Sale	May 13, 2021	9,856	$25.9313	$255,579.19
Open Market Sale	May 14, 2021	11,077	$26.2487	$290,756.85
Open Market Sale	May 17, 2021	6,139	$26.2804	$161,335.38
Open Market Sale	May 18, 2021	4,998	$26.0491	$130,193.40
Open Market Sale	May 19, 2021	7,794	$24.6297	$191,963.88
Open Market Sale	May 20, 2021	7,378	$26.1866	$193,204.73
Open Market Sales	May 21, 2021	6,215	$25.5582	$158,844.21
		4,330	$25.0688	$108,547.90
Exercise of stock options	August 10, 2021	(3,926)	$4.6700	($18,334.42)
Total sales	**95,000**			
Total net sales	**91,074**			
Net proceeds	**$2,496,018.21**			

214. Defendant Schreiber has not sold any shares between November 9, 2021, and the filing of this Complaint. Instead, Defendant Schreiber has acquired 7,852 shares and received 178,510 stock options, which he did not exercise and sell.

215. Hornblower began the Class Period with 3,411,065 shares. During the Class Period, he sold 338,660 shares for proceeds (net of costs of exercising options) of $9,293,806.05. Hornblower's transactions are set out in Exhibit A hereto, which is incorporated by reference.

216. After Defendant Hornblower separated from Shattuck in October 2021, he no longer had any obligation to disclose any of his purchases or sales of Shattuck shares.

D. Loss causation

217. On November 9, 2021, before trading, Shattuck announced that its agreement with Takeda was terminated:

> **Shattuck and Takeda Mutually Agree to Termination of Collaboration Agreement:** In November 2021, Shattuck and Takeda mutually agreed to termination of the Collaboration Agreement for [PD/OX] and SL-115154, originally executed in 2017. Shattuck is no longer required to satisfy any remaining performance obligations, the Company will not make any payments to or receive any future milestone or royalty payments from Takeda, and all options to license and rights of first negotiation held by Takeda under the Collaboration Agreement were terminated.

218. Shattuck had previously told investors it would report the results of PD/OX's initial dose escalation study as well as the three expansion cohorts at the SITC annual meeting taking place November 10-14, 2021. On the morning of November 9, 2021, SITC published abstracts and posters for Shattuck's presentation, including the Poster.

219. Among other things, the Poster revealed the information alleged above in ___, namely that: (a) in the dose escalation portion of the trial, (i) only one patient had a positive objective response, (ii) the rate of clinical response was higher in the patients who received a subtherapeutic dose than in those who received a potentially therapeutic dose, and (iii) patients who received a non-therapeutic dose performed better than patients who received a therapeutic

dose; and (b) as to the Expansion Cohorts, (i) only one patient remained in the trial for more than 8 weeks, and that patient had progressive disease, and (ii) only one patient experienced any stable disease, and not enough to meet the Stable Disease Endpoint. Thus, the data set out in the Poster showed that PD/OX did not work.

220. The revelations that Takeda had terminated the agreement and that PD/OX did not work caused the price of Shattuck's shares to fall from their previous close of $19.04 on November 8 to close at $13.59 on November 9, down $5.45 (28.6%), on heavy volume, damaging investors.

E. Defendants' False and Misleading Statements During the Exchange Act Class Period

221. At the February 17 Presentation, Schreiber stated that:

> And we're generating additional data from those three dose levels [0.3 mg/kg, 1.0 mg/kg, and 3.0 mg/kg] based on and then the selection of those dose levels was based on PK [pharmacokinetic] and pharmacodynamic data that ***was telling us that these were the right place to explore further and we expect to nominate the recommended Phase 2 dose out of one of those three dose levels.***

222. Defendant Schreiber's statement was misleading and made with scienter for failing to disclose that: (a) Takeda had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts, such that Shattuck would have had to conduct the Phase 2 clinical trial without Takeda's financial or technical assistance; (b) the Clinical Trial efficacy data showed that PD/OX was not effective at any dose, including 0.3 mg/kg, 1.0 mg/kg, and 3.0 mg/kg.

223. On March 16, 2021, Defendant Neill delivered a presentation at the Oppenheimer 31st Annual Healthcare Conference. During his presentation, Defendant Neill said, concerning the Takeda Agreement:

> We of course have a JDC structure with Takeda, ***where we get a tremendous amount—the benefit of a tremendous amount of experience at Takeda***. But where we really got to leverage this partnership [sic] to build our company and to build upon the learnings of getting our first drug into the clinic.

224. The highlighted statement was misleading and made with scienter because it referred to Takeda in the present tense while failing to disclose that: (a) Takeda had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts; (b) Takeda had told Shattuck that PD/OX was not working; and (c) Takeda had terminated its participation in the Takeda Agreement.

225. As to PD/OX's efficacy, Defendant Neill stated:

> With this molecule, we believe that significant platform risks have been discharged, which is an important component of our thesis moving forward. In many ways, [PD/OX] can be thought of as a signal replacement strategy, whereby instead of—T cells, instead of receiving the checkpoint PD-L1 interaction, are instead directly stimulated by the activation of OX40 receptors on CD8 positive T cells by our two sets of preformed trimers in each ARC. ***And we believe that the co-localization of these two signals provides synergistic anti-tumor activity in our preclinical models.***
>
> ***Similar to 172154, we see profound evidence of on target OX40 biology. We see OX40 binding, subsequent T cell proliferation and cytokine release and we see, again, migration of these lymphocytes out of the blood and into specific tissues.*** However, the signature is quite a bit different for this molecule as it is OX40 targeting rather than CD40 targeting and there's distinct biology between the two, which we think is incredibly important.
>
> [PD/OX] is currently in Phase 1 clinical development. We are currently in dose escalation and we have dosed through dose level 10 and we are currently expanding the top three dose levels. Upon selection of a recommended Phase 2 dose, we will move into two—one or more expansion cohorts and we anticipate reporting dose escalation data from this study in the second half of 2021.[10]

226. These statements were misleading and made with scienter because by highlighting the link between preclinical efficacy and immune system stimulation, stating that the PD/OX Clinical Trial had achieved immune system stimulation, but not disclosing that the Clinical Trial

[10] The statements in this paragraph are inaccurate. Even by February 17, 2021, Takeda had already selected the dose and dose schedule for the Expansion Cohorts and was even administering PD/OX to patients in the Expansion Cohort. Further, Shattuck had selected 0.3 mg/kg, 1.0 mg/kg, and 3.0 mg/kg, for the Expansion Cohorts, but not 6.0 mg/kg, the highest dose.

had shown a lack of efficacy, Neill gave the misleading impression that the Clinical Trial was demonstrating efficacy. To prevent his statements from being misleading, Neill was required to, but did not, disclose that to date the Phase I trial shown a lack of efficacy.

227. The 2020 10-K provided as to the PD/OX Clinical Trial results:

> Our second product candidate, [PD/OX], being developed in collaboration with Takeda, simultaneously inhibits PD-1 and activates the OX40 receptor. We believe [PD/OX] has the potential to offer a differentiated approach to targeting PD-1 and OX40, as compared to existing antibody therapies, either as individual monotherapies or in combination. To date, antibodies targeting OX40 have not demonstrated sufficient efficacy in clinical trials, a result that we believe is due to a structural mismatch between bivalent antibodies and trimeric OX40 receptors. ***The unique hexameric structure of [PD/OX] is designed to more effectively bind to and activate OX40 receptors, leading to optimized signaling and resulting in T cell activation and proliferation. Together, these properties are intended to replace PD-L1-mediated immune inhibition with OX40 costimulation to synergistically enhance anti-tumor response. In preclinical models, compared to the combination of anti-PD-1 and OX40-agonist antibodies, [PD/OX] demonstrated superior tumor reduction and lymphocyte proliferation and migration to tissues. Our ongoing Phase 1 trial is evaluating [PD/OX] in patients with advanced solid tumors and lymphoma.*** We expect to announce data from the dose-escalation portion of this trial in the second half of 2021. ***Takeda has an exclusive option to license [PD/OX] prior to initiation of a Phase 2 clinical trial***. We expect to announce data from the dose-escalation portion of the [PD/OX] trial in the second half of 2021. ***If the data obtained in these trials are highly compelling, accelerated registration paths and other regulatory designations will be discussed with regulatory agencies.*** However, any such determination will be made in the sole discretion of such regulatory agencies and there can be no guarantee that any of our product candidates will be granted a differentiated regulatory path or designation.
>
> * * * * *
>
> While other programs sought to block PD-1 and activate OX40 signaling by administering multiple therapeutics, [PD/OX] seeks to do so colocalized within a single therapeutic and within the immune synapse. ***Importantly, unlike the bivalent structure of existing antibodies, the hexameric structure of [PD/OX] is designed to effectively trimerize and directly activate OX40 receptors. In preclinical studies, [PD/OX] was found to be a highly potent stimulator of an adaptive immune response, and also demonstrated greater anti-tumor activity than anti-PD-1 antibodies or OX40-agonist antibodies, either alone or in combination.***
>
> * * * * *

> ***Preliminary pharmacodynamic activity has also been evaluated in patients treated across a dose-range of 0.0001 to 3 mg/kg. Post-dose receptor occupancy on OX40-positive lymphocytes was observed in a dose-dependent fashion, and the total number of OX40-positive cells in the blood declined rapidly post-infusion of [PD/OX]. We believe the post-infusion decreases in OX40-positive lymphocytes provides evidence of on-target biology. In NHP [non-human primates], similar post-infusion decreases in lymphocytes were associated with migration of lymphocytes into tissues.*** We expect to select a dose and schedule (either weekly or bi-weekly) to advance into the expansion cohorts, and to report safety, pharmacokinetic and pharmacodynamic data from the dose-escalation portion of this clinical trial in the second half of 2021. We expect to begin enrolling patients in one or more dose-expansion cohorts in the second half of 2021.[11]
>
> ***In our preclinical studies in mice with rapidly growing tumors, murine PD-1-Fc-OX40L achieved superior tumor growth inhibition and improved survival compared with an anti-PD-1 antibody and an OX40 agonist antibody, either alone or in combination, as shown in Figure 7 above.***

228. The emphasized statements were misleading and made with scienter because by highlighting the link between preclinical efficacy and immune system stimulation, stating that the PD/OX Clinical Trial had achieved immune system stimulation, but not disclosing that the Clinical Trial had shown a lack of efficacy, Defendants gave the misleading impression that the Clinical Trial was demonstrating efficacy. Further, Defendants' statement that PD/OX could receive accelerated registration if the PD/OX Clinical Trial data were compelling was misleading because the trial showed PD/OX had failed. To prevent their statements from being misleading, Defendants were required to, but did not, disclose that the Clinical Trial was showing a lack of efficacy. The statements were also misleading for describing Takeda's option to license PD/OX without disclosing that (a) Takeda had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts; (b) Takeda had told Shattuck that

[11] The last two sentences of this paragraph are inaccurate, because by February 17, 2021, Takeda had already selected the dose and dose schedule for the Expansion Cohorts and was even administering PD/OX to patient in the Expansion Cohort.

PD/OX was not showing efficacy; and (c) Takeda had terminated its participation in the Takeda Agreement.

229. As to the Takeda Agreement, the 2020 10-K provided, among other things:

> **Our Strategy**
>
> Our goal is to become the world leader in the discovery, development, and commercialization of dual-sided, bi-functional fusion proteins for the treatment of cancer and autoimmune diseases. We plan to achieve this by utilizing our proprietary ARC and GADLEN platforms to create novel therapeutics to treat patients who lack effective treatment options. Key elements of our strategy include:
>
> * * * * *
>
> ***Collaboration Agreement with Takeda***
>
> On August 8, 2017, we entered into a Collaboration Agreement with Millennium Pharmaceuticals, Inc., or Takeda, a wholly owned subsidiary of Takeda Pharmaceutical Company, Ltd., or the Collaboration Agreement. The Collaboration Agreement was subsequently amended in April 2018, October 2018, and March 2020.
>
> Pursuant to the Collaboration Agreement, we are required to use our commercially reasonable efforts to conduct preclinical and Phase 1 clinical trials for two molecules, [PD/OX] and CSF1R-Fc-CD40L, and ***Takeda has an exclusive option to license one or both of these clinical-stage ARC compounds for a specified amount of time up to and following the conclusion of each respective Phase 1 trial.*** While we are currently evaluating [PD/OX] in a Phase 1 clinical trial, we have not yet conducted a Phase 1 clinical trial for CSF1R-Fc-CD40L. During the development phase of the Collaboration Agreement, we may not, by ourselves or through a third party, develop or commercialize a compound, molecule, or product that targets both PD-1 and OX40L, or a compound, molecule, or product that targets both CSF1R and CD40L.
>
> * * * * *
>
> ***Under the Collaboration Agreement, Takeda is granted a right of first negotiation to enter into licenses for each molecule within a specified class of ARC molecules.*** To exercise its right of first negotiation, Takeda will be required to provide a notice within a specified time, and if the parties do not conclude a license agreement within a set timeframe, we will be entitled to enter into licenses with third parties, subject to certain conditions.

> As of December 31, 2020, under the Collaboration Agreement, we have received approximately $78.4 million in option payments, milestone payments, and expense reimbursements from Takeda. ***If Takeda exercises its exclusive option to license one or both of the clinical-stage ARC compounds ([PD/OX] and CSF1R-Fc-CD40L), we will enter into a license agreement with Takeda with respect to such compound. Any such license agreement would, among other things, require Takeda to use its commercially reasonable efforts to develop the licensed compound and seek approval for the compound. In addition, Takeda would be solely responsible to use its commercially reasonable efforts, at its cost, to develop, manufacture, and commercialize the licensed ARC compounds. If both ARC compounds are licensed, we would be entitled to additional payments of up to an aggregate of $450 million in clinical, regulatory, and sales milestone payments. In addition, we would be eligible for tiered royalty payments on net sales of licensed products at percentages ranging from the high single digits to sub-teens, subject to specified reductions, during the royalty term.***
>
> ***If Takeda exercises its option to enter into a license agreement***, the royalty term with respect to the licensed product would extend, on a country-by-country basis, from the period commencing on the first commercial sale of the product in such country and ending on the later of (i) the expiration of the last to expire of the valid claims on the applicable licensed patent rights covering the product in such country or (ii) the tenth anniversary of the first commercial sale of the product in such country.
>
> Unless sooner terminated, the Collaboration Agreement will continue until the later of (a) the earlier of (i) the 90th day following delivery of a report detailing certain results of the [PD/OX] Phase 1 clinical trial and (ii) the exercise by Takeda of its right to an exclusive license with respect to [PD/OX], and (b) the earlier of (i) the 90th day following delivery of a report detailing certain results of the SL-115154 Phase 1 clinical trial and (ii) the exercise by Takeda of its right to an exclusive license with respect to SL-115154.

230. The statements were misleading and made with scienter for describing Takeda's option to license PD/OX without disclosing that the description was moot because: (a) Takeda had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts; (b) Takeda had told Shattuck that PD/OX was not showing efficacy; and (c) Takeda had terminated its participation in the Takeda Agreement.

231. Under Regulation S-K, Defendants must make the disclosures required by Items 303 and 105 in every annual report on Form 10-K. For the reasons stated in ¶¶115-34, Items 303 and 105 required disclosure that, as Defendants knew or were reckless in not knowing, (a) Takeda

had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts; (b) Takeda had told Shattuck that PD/OX was not showing efficacy; (c) Takeda had terminated its participation in the Takeda Agreement; and (d) the PD/OX Clinical Trial showed a lack of efficacy.

232. On May 5, 2021, Shattuck delivered a presentation at the Truist Securities Life Sciences Summit. In prepared remarks, Schreiber stated:

> ***As I've noted a couple of times now, we are developing [PD/OX] in collaboration with Takeda Pharmaceuticals***. This partnership with Takeda Pharmaceuticals was struck very early in Shattuck's life, even prior to a Series A financing, ***and was absolutely transformational in the way that we built this company. Essentially, Takeda retains an exclusive option to license both [PD/OX] and another molecule in our pipeline and, through the development, through the end of Phase I clinical development***
>
> ***Should Takeda choose to exercise their licenses, we remain eligible to receive licensing payments, of course, as well as escalating development, regulatory, and commercial milestones before a tiered royalty on net sales ranging from the high single digits to the subteens. Upon exercise of the license, Takeda would be responsible development and commercialization.***

233. The highlighted statements were misleading and made with scienter for describing Takeda's option to license PD/OX without disclosing that the description was moot because: (a) Takeda had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts; (b) Takeda had told Shattuck that PD/OX was not showing efficacy; and (c) Takeda had terminated its participation in the Takeda Agreement. The highlighted statements were also misleading for referring to the Takeda agreement in the present tense.

234. Schreiber continued in his prepared remarks:

> Through February 3, [PD/OX] has been generally well tolerated with no DLTs [dose-limiting toxicities] identified. ***And we are seeing pharmacodynamic evidence of OX40 engagement, which suggests to us that the ARC platform has the potential to unlock the TNF receptor biology in a manner not observed with other modalities.***

235. The highlighted statements were misleading and made with scienter because, having highlighted the link between preclinical efficacy and immune system stimulation, stating that the PD/OX Clinical Trial achieved immune system stimulation, and that the evidence of the trial suggests the "ARC platform has the potential to unlock the TNF receptor biology" without also disclosing that the PD/OX Clinical Trial was showing a lack of efficacy, Defendants gave the misleading impression that Shattuck was observing some evidence of efficacy. To prevent their statements from being misleading, Defendants were required to, but did not, disclose that to date the Clinical Trial was showing a lack of efficacy.

236. On August 11, 2021, Shattuck issued a press release to provide an update on, among other things, the Clinical Trial. The August 11 Press Release quoted Defendant Schreiber as saying:

> "Over the past quarter we have begun to compare and contrast the immunological effects of CD40 and OX40 stimulation in cancer patients treated with SL-172154 and [PD/OX]. ***We believe the emerging data validate the hypothesis that the ARC platform can uniquely activate the TNF superfamily and indicate that the effects of OX40 stimulation are far more subtle than innate immune stimulation of CD40.*** We are excited to share this data in just a few months' time at the SITC Annual Meeting,"

237. The August 11 Press Release then provided the basis for Defendant Schreiber's statement:

> **Additional Dose Escalation Cohorts Added to the [PD/OX] Phase 1 Clinical Trial:** An analysis of data collected across a dose range of 0.0001 through 6.0 mg/kg, on two ***dosing schedules, demonstrated dose dependent OX40 receptor engagement of OX40 expressing T cells, and a primary pharmacodynamic effect showing rapid egress of these target cells from circulation. This effect has not been reported for prior OX40 agonist antibodies.*** No dose-limiting toxicities have been observed to date. ***Based on these data Shattuck plans to enroll additional patients at dose levels of 12.0 and 24.0 mg/kg.*** Because very few of the patients treated to date are known to express PD-L1 within the tumor, Shattuck plans to enroll patients with known PD-L1 positive tumors in the additional dose level cohorts. The Phase 1 trial is an open label, multi-center, dose escalation, and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity,

> and pharmacodynamic effects of [PD/OX] as monotherapy in patients with advanced solid tumors. [PD/OX] ***is currently being developed in collaboration with Takeda Pharmaceuticals.*** An abstract containing data from the dose-escalation cohorts through 6.0 mg/kg has been submitted to the SITC Annual Meeting, to be held in November 2021.

238. The August 11 Press Release closed with a description of PD/OX:

> **About [PD/OX]**
> [PD/OX] is an investigational bi-functional fusion protein designed to block the PD-1 immune checkpoint and simultaneously agonize the OX40 pathway. [PD/OX] is currently being evaluated in a Phase 1 clinical trial for the treatment of patients with advanced solid tumors and lymphoma. ***[PD/OX] is part of a collaboration with Takeda Pharmaceuticals. In preclinical studies, [PD/OX], demonstrated evidence of high monotherapy activity, potent stimulation of OX40+ T Cells and superior anti-tumor activity over Anti-PD1/L-1 antibodies and Anti-OX40 antibodies, both alone or in combination.***

239. These statements were misleading and made with scienter because by highlighting the link between preclinical efficacy and immune system stimulation, stating that the Phase I trial had achieved immune system stimulation, and stating that the evidence of the trial "indicate[s] that the effects of OX40 stimulation are far more subtle than innate immune stimulation of CD40" without also disclosing that the PD/OX Clinical Trial showed a lack of efficacy, Defendants gave the misleading impression that Shattuck was observing some evidence of efficacy. To prevent their statements from being misleading, Defendants were required to, but did not, disclose that the Clinical Trial was showing a lack of efficacy. Further, Defendants' claim that the PD/OX was "being developed in collaboration with Takeda Pharmaceuticals" in the present tense is misleading for failing to disclose that (a) Takeda had already told Defendants that it was not interested in licensing PD/OX and would withdraw from the Takeda Agreement as soon as its contractual obligations were terminated, and (b) Takeda had terminated its participation in the Takeda Agreement.

240. On September 15, 2021, Shattuck presented at the Morgan Stanley 19th Annual Global Healthcare Conference. In the presentation, Defendant Schreiber stated:

> Q: Okay. Great. Thank you. Why don't we move to your -- some of your other programs. So know your other clinical program [PD/OX] is partnered with Takeda in the collaboration that [Neill] mentioned earlier. Can you tell us about this product candidate, which also comes out of the ARC platform, as well as provide an overview of the collaboration?
>
> **DEFENDANT SCHREIBER**: Sure. So we've entered into an option to license agreement with Takeda Pharmaceuticals in 2017 for -- including the PD-1 Fc OX40 ligand molecule. And here again, we selected PD-1 as a functional domain for this ARC because that clearly is a clinically validated checkpoint. ***And pairing the PD-1 domain with OX40 ligand was driven by preclinical data, suggesting that, in pairing these -- that the PD-1 immune checkpoint within OX40 ligand domain. We created an anti-tumor benefit, which was much greater than the sum of the parts and greater than what we saw preclinically head-to-head against anti-PD-1, anti-PDL1 or anti-OX40 antibodies.***
>
> And so, this program entered Phase 1 clinical testing and a dose-escalation trial in 2019. And that was actually the first molecule to enter the clinic. And so, it was -- we started at a very, very low dose because this is an immune agonist. And it was the first in man experience for the ARC platform as a whole. And we've now safely dose escalated to six milligrams per kilogram in that trial, ***and seen binding and activation of OX40 positive cells over time.*** And those effects have not yet plateaued. ***And so, that was the reason why we decided to now move beyond the six milligrams per kilogram dose level, and we're enrolling patients at both 12 and 24 milligrams per kilogram.*** Also, because we started at an extremely low dose, the patients were not -- up until this point in time, were not selected on the basis of PD-L1 expression to facilitate enrollment. ***Now that we know we're in immunologically active dose***, we are now selecting for PD-L1 expression greater than 1% on patient tumor cells for eligibility, and we'll be looking to see monotherapy activity in that selected patient population at the 12 or 24 mg/kg dose level in PD-1 refractory patients to justify further development. ***We remain in full control of the program through Phase 1, and Takeda retains an option to license that molecule any time through the end of Phase 1 study.***

241. The statements were misleading and made with scienter because by highlighting the link between preclinical efficacy and immune system stimulation, stating that the Phase I trial had achieved immune system stimulation, and stating that in the Clinical Trial Shattuck had "seen binding and activation of OX40 positive cells over time" and that Shattuck is "in immunologically active dose", without also disclosing that the PD/OX Clinical Trial showed no evidence of efficacy, Defendants gave the misleading impression that Shattuck was observing some evidence of efficacy. To prevent their statements from being misleading, Defendants were required to, but did not, disclose that to date the Phase I trial had not shown efficacy. Further, Defendants' claim

that the PD/OX was "being developed in collaboration with Takeda Pharmaceuticals" in the present tense is misleading and made with scienter because: (a) Takeda had told Shattuck it would not license PD/OX and would only satisfy its contractual obligations to fund the Expansion Cohorts; (b) Takeda had told Shattuck that PD/OX was not showing efficacy; and (c) Takeda had terminated its participation in the Takeda Agreement.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

242. During the entire Class Period, the market for the Company's common stock was an efficient market for the following reasons, among others:

(a) The Company's common stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient, electronic stock market;

(b) As a regulated issuer, the Company filed periodic public reports with the SEC;

(c) The Company regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) The Company was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

243. As a result of the foregoing, the market for the Company's common stock promptly digested current information concerning the Company from all publicly available sources and reflected such information in the prices of the Company's stock. Under these circumstances, all purchasers of the Company's common stock during the Class Period suffered similar injury

through their purchase of the Company's common stock at artificially inflated prices and a presumption of reliance applies.

XI. COUNT III

Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder Against All Exchange Act Defendants

244. Plaintiffs repeat and reallege each and every allegation contained above as though set forth in full herein.

245. During the Class Period, Exchange Act Defendants disseminated or approved the materially false and misleading statements specified above, which they knew, or were deliberately reckless in not knowing, were misleading. These statements were false and misleading because they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

246. Exchange Act Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact/and or omitted to state material facts necessary to make the statements made not misleading; and (3) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period.

247. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiffs and the Class would not have purchased the Company's common stock at the prices they paid—or at all—if they had been aware that the market prices had been artificially and falsely inflated by Exchange Act Defendants' misleading statements.

248. As a direct and proximate result of Section 10(b) Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

XII. COUNT IV

Violations of Section 20(a) of the Exchange Act Against the Individual Exchange Act Defendants

249. Plaintiffs repeat and reallege each and every allegation contained above as though set forth in full herein.

250. The Individual Exchange Act Defendants acted as controlling persons of the Company within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and/or intimate knowledge of the Company's statements filed with the SEC and disseminated to the investing public, the Individual Exchange Act Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements alleged to be false and misleading herein.

251. The Individual Exchange Act Defendants, moreover, were provided with, or had unlimited access to, copies of the Company's reports, press releases, public filings, and other statements alleged to be false and misleading herein. The Individual Exchange Act Defendants were provided with, or had unlimited access to, such documents and statements prior to, and/or shortly after these statements were issued, and therefore had the ability to prevent the issuance of the statements and/or cause the statements to be corrected. Additionally, the Individual Section 10(b) Defendants had direct and supervisory involvement in the day-to-day operations of the

Company and had the power to control or influence the particular transactions giving rise to the securities violations.

252. The Individual Exchange Act Defendants all had ultimate authority over the Company's statements, including controlling the content of such statements and whether and how to communicate such statements to the public.

253. By reason of such conduct, the Individual Exchange Act Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XIII. COUNT V

Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5-1 Promulgated Thereunder Against the Individual Exchange Act Defendants for Trading While in Possession of Material Non-Public Information

254. The Individual Exchange Act Defendants, were in possession of material non-public information at the time they sold shares during the Class Period, namely the facts set out above, including: (a) that the Clinical Trial showed that PD/OX was not effective; (b) that Takeda had told Shattuck it was not interested in licensing PD/OX; (c) that Takeda had told Shattuck the Clinical Trial did not show any evidence of efficacy, and (d) that Takeda had shuttered the Takeda Team responsible for collaborating with Shattuck ("Omitted Facts").

255. The Individual Exchange Act Defendants knew these Omitted Facts were material to Shattuck investors.

256. As the sellers of more than $10 million of stock during the Class Period, the Individual Exchange Act Defendants had a duty to either (a) refrain from selling stock, or (b) to disclose the Omitted Facts.

257. The Individual Exchange Act Defendants sold shares to investors while in possession of material non-public information.

258. Plaintiffs and Class Members purchased Shattuck shares contemporaneously with Individual Exchange Act Defendants' sale of shares.

259. The Individual Exchange Act Defendants are liable to all persons purchasing Shattuck shares contemporaneously with their sales.

XIV. COUNT VI

Violations of §20A of the Exchange Act Against the Individual Exchange Act Defendants

260. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. Count IV is brought pursuant to §20A of the Exchange Act against the Individual Exchange Act Defendants, on behalf of Plaintiffs who were damaged by the Individual Exchange Act Defendants' insider trading

261. As detailed herein, the Individual Exchange Act Defendants were in possession of material, non-public information concerning Shattuck. The Individual Exchange Act Defendants took advantage of their possession of material, non-public information regarding Shattuck to obtain millions of dollars in insider trading profits during the Class Period.

262. The sales of common stock of the Individual Exchange Act Defendants were made contemporaneously with Plaintiffs' purchases of Shattuck common stock during the Class Period: [contemporaneous purchaser chart]

263. Plaintiffs who purchased shares of Shattuck common stock contemporaneously with sales by the Individual Exchange Act Defendants suffered damages because: (1) in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of §§10(b) and 20(a) of the Exchange Act as alleged herein; and (2) they would not have purchased the securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the false and misleading statements and concealment alleged herein.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, pray for judgment and relief as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as Class representatives;

B. Awarding damages in favor of Plaintiffs and other Class members against all Defendants, jointly and severally, together with interest thereon;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest; and

D. Awarding Plaintiffs and the other members of the Class such other and further relief as the Court may deem just and proper.

Dated: July 1, 2022

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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